

WHAT IS CLAIMED:

- 1           1. A method for treating an autoimmune disease in a  
2 mammal, the method comprising administering to said mammal an  
3 effective amount for treating said disease of a bystander  
4 antigen, said antigen eliciting the release of transforming  
5 growth factor beta (TGF- $\beta$ ) at a locus within the body of said  
6 mammal wherein T cells contributing to autoimmune response are  
7 found to suppress the T-cells contributing to said response.
- 1           2. The method of claim 1 wherein said bystander  
2 antigen is specific to an organ or tissue afflicted by immune  
3 attack during said disease.
- 1           3. The method of claim 2 wherein said bystander  
2 antigen is not an autoantigen.
- 1           4. The method of claim 2 wherein said bystander  
2 antigen is an autoantigen.
- 1           5. The method of claim 2 wherein said bystander  
2 antigen comprises a portion of an autoantigen but excludes at  
3 least one epitope of said autoantigen that is recognized by  
4 immune system cells contributing to said disease.
- 1           6. The method of claim 1 wherein said bystander is  
2 administered to said mammal via oral route.
- 1           7. The method of claim 1 wherein said bystander is  
2 administered to said mammal via inhalation.
- 1           8. The method of claim 1 wherein:  
2               said bystander antigen is administered by oral  
3 route or by inhalation;  
4               said oral or inhalable bystander antigen elicits  
5 suppressor T-cells that cause the release of TGF- $\beta$ ;

6           said bystander antigen is not specific to an  
7 organ or tissue afflicted by immune attack during said disease;  
8           said method further comprising also:  
9 administering to said mammal the same bystander antigen via  
10 parenteral route, thereby causing said suppressor T-cells to be  
11 targeted to the same loci within the body of said mammal  
12 wherein the cells contributing to autoimmune attack are found.

1           9. The method of claim 1 wherein said disease is  
2 selected from the group of multiple sclerosis and animal models  
3 therefor, and said bystander antigen is selected from the group  
4 of myelin basic protein, proteolipid protein, fragments thereof  
5 comprising at least one suppressive epitope, and combinations  
6 of any two of the foregoing.

1           10. The method of claim 9 wherein said bystander  
2 antigen comprises MBP peptide 21-40.

1           11. The method of claim 1 wherein said disease is  
2 selected from the group consisting of rheumatoid arthritis and  
3 animal models therefor and said bystander antigen is selected  
4 from the group consisting of Type I collagen, Type II collagen,  
5 fragments thereof comprising a suppressive epitope and  
6 combinations of two or more of the foregoing.

1           12. The method of claim 1 wherein said disease is  
2 selected from the group consisting of Type I diabetes and  
3 animal models therefor and said bystander antigen is selected  
4 from the group consisting of glucagon, insulin, fragments  
5 thereof comprising at least one suppressive epitope, and  
6 combinations of two or more of the foregoing.

1           13. The method of claim 1 wherein said disease is  
2 selected from the group consisting of uveoretinitis and animal  
3 models therefor and said bystander antigen is selected from the

4 group consisting of S-antigen, interphotoreceptor retinoid  
5 binding protein (IRBP), fragments thereof comprising at least  
6 one suppressive epitope, and combinations of two or more of the  
7 foregoing.

1 14. The method of claim 1 further comprising  
2 administering to said mammal an amount of a synergist effective  
3 in combination with said bystander antigen to treat said  
4 disease.

1 15. A pharmaceutical oral dosage form for treating  
2 an autoimmune disease in a mammal, the form comprising:  
3 an effective amount for treating said disease of  
4 a bystander antigen, said antigen upon administration eliciting  
5 the release of transforming growth factor beta (TGF- $\beta$ ) at a  
6 locus within the body of said mammal wherein T cells  
7 contributing to autoimmune response are found to suppress the  
8 T-cells contributing to said response; and  
9 a pharmaceutically acceptable carrier or  
10 diluent.

1 16. The oral dosage form of claim 15 wherein said  
2 bystander antigen is specific to an organ or tissue afflicted  
3 by immune attack during said disease.

1 17. The oral dosage form of claim 16 wherein said  
2 bystander antigen is not an autoantigen.

1 18. The oral dosage form of claim 16 wherein said  
2 bystander antigen is an autoantigen.

1 19. The oral dosage form of claim 16 wherein said  
2 bystander antigen comprises a portion of an autoantigen  
3 comprising an immunosuppressive epitope but excludes at least

4 one epitope of said autoantigen that is recognized by immune  
5 system cells contributing to said disease.

1           20. The oral dosage form of claim 15 wherein said  
2 disease is selected from the group of multiple sclerosis and  
3 animal models therefor, and said bystander antigen is selected  
4 from the group of myelin basic protein, proteolipid protein,  
5 fragments thereof comprising at least one suppressive epitope,  
6 and combinations of any two of the foregoing.

1           21. The oral dosage form of claim 20 wherein said  
2 bystander antigen comprises MBP peptide 21-40.

1           22. The oral dosage form of claim 15 wherein said  
2 disease is selected from the group consisting of rheumatoid  
3 arthritis and animal models therefor and said bystander antigen  
4 is selected from the group consisting of Type I collagen, Type  
5 II collagen, fragments thereof comprising a suppressive epitope  
6 and combinations of two or more of the foregoing.

1           23. The oral dosage form of claim 15 wherein said  
2 disease is selected from the group consisting of Type I  
3 diabetes and animal models therefor and said bystander antigen  
4 is selected from the group consisting of glucagon, insulin,  
5 fragments thereof comprising at least one suppressive epitope,  
6 and combinations of two or more of the foregoing.

1           24. The oral dosage form of claim 15 wherein said  
2 disease is selected from the group consisting of uveoretinitis  
3 and animal models therefor and said bystander antigen is  
4 selected from the group consisting of S-antigen,  
5 interphotoreceptor retinoid binding protein (IRBP), fragments  
6 thereof comprising at least one suppressive epitope, and  
7 combinations of two or more of the foregoing.

1           25. The oral dosage form of claim 15 further  
2 comprising administering to said mammal an amount of a  
3 synergist effective in combination with said bystander antigen  
4 to treat said disease.

1           26. A pharmaceutical inhalable dosage form for  
2 treating an autoimmune disease in a mammal, the form  
3 comprising:  
4                 an effective amount for treating said disease of  
5 a bystander antigen, said antigen upon administration eliciting  
6 the release of transforming growth factor beta (TGF- $\beta$ ) at a  
7 locus within the body of said mammal wherein T cells  
8 contributing to autoimmune response are found to suppress the  
9 T-cells contributing to said response; and  
10                 a pharmaceutically acceptable carrier or  
11 diluent.

1           27. The inhalable dosage form of claim 26 wherein  
2 said bystander antigen is specific to an organ or tissue  
3 afflicted by immune attack during said disease.

1           28. The inhalable dosage form of claim 26 wherein  
2 said bystander antigen is not an autoantigen.

1           29. The inhalable dosage form of claim 26 wherein  
2 said bystander antigen is an autoantigen.

1           30. The inhalable dosage form of claim 26 wherein  
2 said bystander antigen comprises a portion of an autoantigen  
3 comprising an immunosuppressive epitope but excludes at least  
4 one epitope of said autoantigen that is recognized by immune  
5 system cells contributing to said disease.

1           31. The inhalable dosage form of claim 26 wherein  
2 said disease is selected from the group of multiple sclerosis

3 and animal models therefor, and said bystander antigen is  
4 selected from the group of myelin basic protein, proteolipid  
5 protein, fragments thereof comprising at least one suppressive  
6 epitope, and combinations of any two of the foregoing.

1 32. The inhalable dosage form of claim 31 wherein  
2 said bystander antigen comprises MBP peptide 21-40.

1 33. The inhalable dosage form of claim 26 wherein  
2 said disease is selected from the group consisting of  
3 rheumatoid arthritis and animal models therefor and said  
4 bystander antigen is selected from the group consisting of Type  
5 I collagen, Type II collagen, fragments thereof comprising a  
6 suppressive epitope and combinations of two or more of the  
7 foregoing.

1 34. The inhalable dosage form of claim 26 wherein  
2 said disease is selected from the group consisting of Type I  
3 diabetes and animal models therefor and said bystander antigen  
4 is selected from the group consisting of glucagon, insulin,  
5 fragments thereof comprising at least one suppressive epitope,  
6 and combinations of two or more of the foregoing.

1 35. The inhalable dosage form of claim 26 wherein  
2 said disease is selected from the group consisting of  
3 uveoretinitis and animal models therefor and said bystander  
4 antigen is selected from the group consisting of S-antigen,  
5 interphotoreceptor retinoid binding protein (IRBP), fragments  
6 thereof comprising at least one suppressive epitope, and  
7 combinations of two or more of the foregoing.

1 36. The inhalable dosage form of claim 26 further  
2 comprising administering to said mammal an amount of a  
3 synergist effective in combination with said bystander antigen  
4 to treat said disease.

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